disease activity and lab measurements. **RESULTS:** 106 papers met our inclusion criteria. Studies were published between 2003 and 2015 and mostly from Europe; 39 included patients starting etanercept, 36 included patients starting rituximab and 32 patients starting tocilizumab. Mean age ranged between 42.9 and 63.3 years, 78.2% were female. The drugs were given in combination with methotrexate and/or other traditional DMARDs in over two thirds of the studies. Mean disease duration varied between 4 and 17.5 years, baseline disease activity 28 scores between 4.3 and 7.0, and baseline health assessment questionnaire values between 1 and 2.9. The mean percentage of rheumatoid-factor positive patients was 76.4%. Reporting of comorbidities and smoking status was generally poor, with only few studies providing detailed data. **CONCLUSIONS:** This systematic review of data from observational studies and clinical databases indicates that the characteristics of RA patients starting biological DMARDs outside clinical trials in the real world varied widely. These observational data will now be compared with clinical trial data but it seems likely that some patient groups were not well represented in the trials.

PMS136
EFFECTIVENESS OF A REFERRAL PROGRAM FOR EARLY ARTHRITIS DIAGNOSIS AT PRIMARY CARE CENTERS IN PORTUGAL - PRELIMINARY RESULTS FROM THE SIARA STUDY

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OBJECTIVES: Early diagnosis and treatment of inflammatory arthritis can limit the impact of disease outcomes. We aimed to evaluate the effectiveness of a referral program on the identification of patients with suspected inflammatory arthritis. **METHODS:** SIARA (Referral Strategies and Disease Education Impact on Diagnosis and Referral of Axial Spondyloarthritis and Rheumatoid Arthritis Patients) is an observational prospective, randomized (by clusters of primary care centers) study to analyze the impact of Referral Support Actions (RSA) consisting of physician educational sessions about the disease and implementation of referral recommendations. The participating primary care centers (n=24) were randomly assigned to RSA or control group (with no intervention). Both RSA and control groups identified and referred patients with suspected inflammatory arthritis to the rheumatology unit of the reference hospital (n=6). The main studied outcome is the correct diagnosis of inflammatory arthritis / rheumatoid arthritis confirmed by the rheumatologist of the reference hospital. **RESULTS:** A total of 125 patients were referred to a rheumatologist (considering 4 hospitals): 61 RSA patients and 64 control patients. Mean age was 48.9 years (range: 19-73) and 88.8% were female (differences not statistically significant between groups). About 14.8% (n=9) of RSA patients and 4.7% (n=3) of controls had a confirmed diagnosis of arthritis (any type) by the rheumatologist (OR=3.5; 95%CI, 0.9-13.7; Chi-square p=0.056). Rate of confirmed rheumatoid arthritis was 4.9% in RSA patients and 1.6% in controls (p=0.287). The majority of the patients (82.0%) were referred in the 4 months after educational session (month 3:63.9%; month 6:96.7%). **CONCLUSIONS:** Although the study results still lack statistical significance, this preliminary data already suggests a positive impact of a referral program on the early identification of inflammatory arthritis, especially after the first few months. This should be further analyzed and considered by healthcare deciders in order to improve health outcomes in inflammatory arthritis.

PMS137
A WEB-BASED SURVEY TO INVESTIGATE THE EXTENT OF AWARENESS AND UNDERSTANDING FOR BIOSIMILAR AMONG JAPANESE PHYSICIANS AND PHARMACISTS

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OBJECTIVES: Several biosimilar products have been developed and marketed in Japan. However, the degree of understanding of biosimilars among healthcare professionals is uncertain. The objective of this study was to investigate the extent of awareness and understanding of biosimilars among Japanese physicians and pharmacists. **METHODS:** This was a non-interventional, web-based survey conducted in May 2015. Japanese physicians (rheumatologists/oncologists) and pharmacists voluntarily participated and provided their thoughts via questionnaires. Rheumatologists who have seen >= 30 rheumatoid arthritis patients/month on average and have prescribed biologics (Remicade/Humira, etc.) to at least one patient, and oncologists who have seen >= 30 cancer patients/year with use of biologics (Rituxan/Avastin/Herceptin, etc.) to at least one patient were eligible. **RESULTS:** Of screened physicians, about 35% have never heard of "biosimilar", whereas 96% of pharmacists were aware of "biosimilar". One hundred rheumatologists, 120 oncologists (30 each for Hematology/Breast/Gastroenterology/Respiratory) and 90 pharmacists who met the criteria and were aware of biosimilar were analyzed for a further questionnaire. 73% of rheumatologists and 82% of oncologists recognized that biosimilars "are relatively less expensive" and 62% of physicians simply answered "subsequent product/generic". 58% of rheumatologists showed an intention to prescribe future biosimilars, whereas 73% of oncologists showed prescription intention. The main reason behind this was "reduction of burden on patients", followed by "confirmed similarity in efficacy/safety". Physicians with little intention to prescribe biosimilars showed strong concerns for similarity to the innovator (>70%) and insufficient clinical data in efficacy/safety perspectives. Similarities in clinical efficacy/safety were more emphasized compared to structural and functional similarities in biosimilar development pathways. **CONCLUSIONS:** Awareness of biosimilars amongst Japanese physicians was still low with a strong leaning toward burden on patients and sufficient clinical data to confirm the similarity. Providing learning opportunities for general tenets of biosimilarity and its development pathways are vital to increase public recognition of biosimilars.

PMS138
ASSESSMENT OF RISK SHARING AGREEMENTS (RSAS) IN SELECT GLOBAL MARKETS WITH SPECIFIC FOCUS ON ACTIVITIES SURROUNDING IMMUNOMODULATORS

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OBJECTIVES: To understand current Risk Sharing Agreements (RSAs) for immunomodulators for rheumatoid arthritis, psoriasis, and psoriatic arthritis in 11 markets aimed to optimize specific RSA strategies/ payer partnerships. **METHODS:** Review of publicly available health authority websites and peer-reviewed journals. Interviews with payers and stakeholders who influence RSA decisions and ex-pharma executives for validation and gap filling. **RESULTS:** USA manufacturers negotiate RSAs with private health insurers and states. Payers in USA integrate financial risks with manufacturers using outcome based agreements (OBAs). Canada established RSAs with Provinces and use financial based agreements (FBAs) but some are OBAs. France requires volume based FBAs for new high-priced therapies to limit budget impact. Germany uses FBAs at the sickness fund level rather than the Gemeinsamer Bundesausschuss (G-BA) level because sickness funds manage their own budgets. Some OBAs exist with clearly defined outcomes. Italy negotiates RSAs at the national level for new therapies entering the market ranging from FBAs to OBAs depending on the specific therapy and target patient population. Italy may also require manufacturers to incorporate drug monitoring registries in the RSA. In Spain performance based OBAs are used for new therapies with nominal additional benefit at the regional level with clearly established outcomes. Netherlands and Sweden use evidence development (CED) agreements for high priced products to generate cost effectiveness data. In Switzerland, RSAs are new and mostly FBAs and mainly for orphan disease therapies and off-label indications with price capping. In the UK,FBAs with few OBAs are used affecting product price but are not rebate based. Australian RSAs are mostly FBAs and are referred to as "Deeds of Agreement." **CONCLUSIONS:** With high-cost immunomodulators, authorities are shifting towards integrating RSAs in price negotiations to optimize budget expectations prior to launch. Europe prefers FBAs to OBAs which often require clearly defined outcomes.

SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

PSY1
ASSOCIATION OF ADVERSE EVENTS AND HEALTH SERVICE USAGE WITH TAPENTADOL PROLONGED-RELEASE TREATMENT COMPARED WITH MORPHINE CONTROLLED-RELEASE (CR) AND OXYCODONE CR: A UK PRIMARY CARE OBSERVATIONAL STUDY

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OBJECTIVES: This study compared adverse outcomes and resource use in patients treated with tapentadol prolonged-release (PR) with those treated with morphine controlled-release (CR) and oxycodone CR. **METHODS:** Data were from the Clinical Practice Research Datalink, a database derived from UK primary-care. Patients prescribed tapentadol PR between May 2011 and December 2014 were matched to two groups of controls treated with either morphine CR or oxycodone CR on gender, age, pain duration, pain site and aetiology, Charlson index and prior analgesia. Rates of adverse events (constipation and nausea/vomiting) were compared by adjusted hazard ratio (aHR). Rates of primary-care contacts, accident and emergency contacts, outpatient clinic letters and, for a subset of patients linked to Hospital Episode Statistics (HES), inpatient admissions were compared using incident rate ratios (IRRs) derived from Poisson regression. **RESULTS:** 1,176 patients prescribed tapentadol PR were identified; 1,103 (93.8%) had a pain diagnosis. Of these 789 (67.1%) were matched to morphine controls and 557 (47.4%) to oxycodone controls. Compared with controls, adverse events with tapentadol PR treatment were reduced: aHR=0.643 (95% CI 0.459–0.901; p=0.010) versus morphine CR and 0.505 (0.335–0.763; p=0.001) versus oxycodone CR. Compared with morphine CR, primary-care contacts (IRR=0.817; 0.786–0.850), accident and emergency attendance (0.699; 0.560–0.870) and outpatient letters (0.715; 0.543–0.939) were also reduced. For oxycodone CR, the respective figures were 0.776 (0.706–0.840), 0.840 (0.639–1.103) and 0.545 (0.400–0.739). For the subset of HES-linked patients the rates of inpatient admissions were 0.723 (0.590–0.884) and 0.458 (0.357–0.585) vs. morphine CR and oxycodone CR, respectively. **CONCLUSIONS:** Tapentadol PR was associated with significantly fewer adverse gastrointestinal events than morphine CR or oxycodone CR. There was also significantly reduced primary- and secondary-care resource use. As with all observational studies, potential bias due to residual confounding and confounding by indication should be considered.

PSY2
CLINICAL AND ECONOMIC BURDEN OF PULMONARY EXCERBATIONS IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION

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OBJECTIVES: To assess the clinical and economic burden of pulmonary exacerbations (PEx) in patients with cystic fibrosis (CF) and homozygous for the F508del CFTR gene mutation. **METHODS:** Medical chart data from patients with CF ≥12 years old were collected in France, Germany, Italy, Spain, Australia and Canada. Demographics, clinical characteristics, and selected resource utilization were obtained for a 12-month baseline period and a follow-up period ranging from 2-36 months. The frequency of PEx and associated resource utilization was assessed overall and by age (12-17, ≥18 years) and lung function (percent predicted forced expiratory volume in 1-second [ppFEV1] ≥70%, 41-69%, ≤40%). Descriptive analyses were conducted. **RESULTS:** Data for 523 patients were included. Baseline mean ± SD age was 24.8 ± 9.5 years and mean ± SD ppFEV1 was 67.1 ± 22.9%. During